UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/771,931 | 02/04/2004 | Harry S. Courtney | 20638/1203595-US1 | 4163 |

7278 7590 03/08/2006

DARBY & DARBY P.C.
P. O. BOX 5257
NEW YORK, NY 10150-5257

| EXAMINER | |
|---|---|
| BASKAR, PADMAVATHI | |
| **ART UNIT** | **PAPER NUMBER** |
| 1645 | |

DATE MAILED: 03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/771,931 | COURTNEY, HARRY S. | |
| | Examiner | Art Unit | |
| | Padmavathi v. Baskar | 1645 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 8-13, and 14-18 drawn to a composition or fusion protein or cocktail comprising *S. pyogenes* serum opacity factor polypeptides classified in class 424 subclass 185.1

(Further restriction to one SOF/SEQ.ID.NO is required, see Para # 4)

II. Claims 5-7, drawn to a composition comprising Group C *Streptococcus dysgalactiae* fibronectin binding proteins classified in class 530, subclass 350.

(Further restriction to one SOF/SEQ.ID.NO is required, see Para # 4)

III. Claims 19-22, drawn to an antibody classified in class 530, subclass 387.1.

(Further restriction to one SOF/SEQ.ID.NO is required, see Para # 4)

IV. Claims 23-26, 27- 31 and 32-36, drawn to a method for eliciting an in vivo antibody response using composition or fusion protein or a cock tail comprising S. pyogenes serum opacity factor polypeptides classified in class 424, subclass 184.1.

(Further restriction to one SOF/SEQ.ID.NO is required, see Para # 4)

V. Claims 37-40, drawn to a method of treating using antibodies, classified in class 424, subclass 130.1

(Further restriction to one SOF/SEQ.ID.NO is required, see Para # 4)

2. The inventions are distinct, each from the other because of the following reasons...

Inventions I-III are patentably distinct products.

The polypeptides of group I and II are drawn to structurally distinct polypeptides from two different Streptococci, namely *S.pyogenes* (group A) and Streptococcus dysgalactiae (group C). The polypeptides of group I / II and antibodies of group III are patentably distinct as

polypeptides, which are composed of amino acids are structurally distinct molecules from antibody of group III whereas group III encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementary determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of group I/II and the antibody of group III are structurally distinct molecules; any relationship between a polypeptide of group II and an antibody of group III is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

3. Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of inducing an antibody response in a mammal and the method of treating a mammal using antibodies are unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for inducing an immune response differ significantly than treating a mammal because polypeptides and adjuvant are administered to inducing an antibody response, however treatment of an infection requires identifying an individual with infection and administering antibodies. Therefore, each method is divergent in materials and steps. For these reasons the Inventions IV, and V are patentably distinct.

**DISTINCT INVENTIONS**

4. For each group of inventions I-V above, restriction to one of the following one SEQ ID NO /serum opacity factor (SOF) is also required. Therefore, election is required of one of inventions I-V and one composition or fusion protein or cocktail or a method of inducing an antibody immune response or method of treatment using one SOF/SEQ ID NO.
SOF 2, Sof4, SOF28 etc/SEQ.ID.NOS 1, 3, 5 etc represent structurally different polypeptides. Therefore, where structural identity is required, such as for expression, the sequences have different effects. Thus, each sequence is patentably distinct and unique
Applicant is required under Restriction is required under 35 U.S.C. 121 to elect a single disclosed SEQ.ID.NO from any group elected. If the polypeptide is associated with specific epitope, applicant should identify and inform the examiner clearly with specific epitope sequence.

5. Inventions I/II and IV/V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide can be used to catalyze an enzymatic reaction as opposed to its use in a method of inducing an immune response or method of treating an infection.

6. Inventions III and IV/V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies can be used to purify antigens in an immuno

Chromatograpy opposed to its use in a method of inducing an immune response. or method of treating an infection.

7. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

11. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for

patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Applicant is required, in reply to this action, to elect a group and one sequence and identify the SEQ.ID.NO to which the claims shall be restricted. The reply must also identify the claims readable on the elected invention, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

13. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either

instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

14. Concerning the burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The DNA database searches required by each of the sequences and the literature searches for each of the sequences, both of which are particularly relevant in this art, are not co-extensive and are much more important in evaluating the burden of search. Further, it is doubted that applicants would readily accept the rejection of one sequence by the application of art teaching another sequence. Clearly different searches and issues are involved in the examination of each group.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor ship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

16. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Padma Baskar Ph.D.

LYNETTE R. F. SMI
SUPERVISORY PATENT EXAM
TECHNOLOGY CENTER 16